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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,674	02/28/2002	Johannes Bartholomacus	148/50986	2545
23911	7590	03/23/2006	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,674

Applicant(s)

BARTHOLOMAEUS ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-67 is/are pending in the application.
- 4a) Of the above claim(s) 10,13,14,16,19,20,22-29,33-54 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11,12,15,17,18,21,30-32 and 55-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response and petition for extension of time, both received on 04 January 2006.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 3-67 under 35 U.S.C. 112, first paragraph, for enablement, is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3-9, 11, 12, 15, 17, 18, 21, 30-32, and 55-58 under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.* in view of Sackler *et al.* is maintained.

Response to Arguments

Applicant's arguments filed 04 January 2006 have been fully considered but they are not persuasive. With regard to the enablement rejection of record, the basis of the examiner's rejection of these claims was not that the specific embodiments provided in the instant

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specification and in the declaration of 25 May 2004 were non-functional. These particular embodiments have been shown by the record to function as claimed by the applicant.

However, the applicant's invention as presently claimed encompasses such a wide and varied range of active agents that the examiner cannot consider that scope to be properly supported by the instant specification. In the view of the examiner, it is not permissible to assert that the full scope of the instant claims is enabled by the instant specification simply because the solubility properties of all the active agents the claims encompass could be within the possession of the applicant at the instant application was filed. The examiner simply cannot find evidence on the record that the applicant had actual knowledge of the solubility properties of all possible active agents encompassed by the scope of the instant claims. Thus far, the instantly claimed invention is enabled only for salts of tramadol and promethazine. To extrapolate from these two particular species in order to support the vast scope of active agents encompassed in the instantly claimed invention is something that has not been properly justified in the instant specification or in the prosecution record of this case.

Additionally, the applicant's citations to the instant specification used to rebut the scope of enablement rejection of record do not properly correspond to applicant's arguments. In the instant specification, page 3, lines 12-17 are part of a larger listing of various types of active agents, in section 0013, rather than salt formation. Page 5, line 28 to page 6, line 5 discusses retarding coatings and page 6, lines 18-23 discusses softeners for the retarding coatings, rather than a list of compounds for salt formation with the active substance; this citation includes sections 27, 28 and 30-32 in the instant specification. Page 17, lines 13-31, corresponding to Example 4, describes the manufacture of pellets, rather than describing a method for determining

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the water solubility of a salt of an active agent. The last three citations given in the response do correspond to their stated content. However, these portions of the specification do not demonstrate an enablement of the additional species beyond tramadol and promethazine that is commensurate with the scope of the instant claims. Therefore, the examiner will maintain the scope of enablement rejection of record.

In regard to the applicant's arguments against the prior art rejection under 35 U.S.C. 103(a), as the applicant has acknowledged, the prior art does teach opioid analgesics and salts thereof and mixtures of the foregoing. The examiner simply interprets this disclosure broadly to mean that mixtures of salts of such active agents are disclosed in the prior art. In the view of the examiner, such an interpretation is broad yet reasonable. Therefore, the prior art rejection of record will be maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

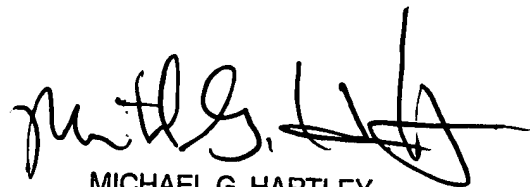
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER